Senate File 436 - Introduced

SENATE FILE 436
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO SSB 1072)

A BILL FOR

An Act relating to the use of step therapy protocols for prescription drugs by health carriers, health benefit plans, and utilization review organizations, and including applicability provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. LEGISLATIVE FINDINGS. The general assembly finds and declares the following:

1. Health carriers, health benefit plans, and utilization review organizations are increasingly making use of step therapy protocols under which covered persons are required to try one or more prescription drugs before coverage is provided for another prescription drug selected by the covered person's health care professional.

2. Such step therapy protocols, where they are based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of covered persons, can play an important part in controlling health care costs.

3. In some cases, requiring a covered person to follow a step therapy protocol may have adverse and even dangerous consequences for the covered person, who may either not realize a benefit from taking a particular prescription drug or may suffer harm from taking an inappropriate prescription drug.

4. Without uniform policies in the state for step therapy protocols, all covered persons may not receive equivalent or the most appropriate treatment.

5. It is imperative that step therapy protocols in the state preserve the health care professional's right to make treatment decisions that are in the best interest of the covered person.

6. It is a matter of public interest that the general assembly require health carriers, health benefit plans, and utilization review organizations to base step therapy protocols on appropriate clinical practice guidelines or published peer review data developed by independent experts with knowledge of the condition or conditions under consideration; that covered persons be excepted from step therapy protocols when inappropriate or otherwise not in the best interest of the covered persons; and that covered persons have access to a fair, transparent, and independent process for allowing a covered person or a health care professional to request an

exception to a step therapy protocol when the covered person's health care professional deems appropriate.

Sec. 2. NEW SECTION. **514F.7 Use of step therapy protocols.**

1. *Definitions.* For the purposes of this section:

a. "Authorized representative" means the same as defined in section 514J.102.

b. "Clinical practice guidelines" means a systematically developed statement to assist health care professionals and covered persons in making decisions about appropriate health care for specific clinical circumstances and conditions.

c. "Clinical review criteria" means the same as defined in section 514J.102.

d. "Covered person" means the same as defined in section 514J.102.

e. "Health benefit plan" means the same as defined in section 514J.102.

f. "Health care professional" means the same as defined in section 514J.102.

g. "Health care services" means the same as defined in section 514J.102.

h. "Health carrier" means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, including an insurance company offering sickness and accident plans, a health maintenance organization, a nonprofit health service corporation, a plan established pursuant to chapter 509A for public employees, or any other entity providing a plan of health insurance, health care benefits, or health care services. *"Health carrier"* includes an organized delivery system. *"Health carrier"* does not include a managed care organization as defined in 441 IAC 73.1 when the managed care organization is acting pursuant to a contract with the Iowa department of human services to provide services to Medicaid recipients.

i. "Medical necessity" means health care services and

supplies that under the applicable standard of care are appropriate for any of the following:

(1) To improve or preserve health, life, or function.

(2) To slow the deterioration of health, life, or function.

(3) For the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

j. "Step therapy override exception" means a step therapy protocol should be overridden in favor of immediate coverage of the prescription drug selected by a health care professional. This determination is based on a review of the covered person's or health care professional's request for an override, along with supporting rationale and documentation.

k. "Step therapy protocol" means a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular covered person are covered under a pharmacy or medical benefit by a health carrier, a health benefit plan, or a utilization review organization, including self-administered drugs and drugs administered by a health care professional.

l. "Utilization review" means a program or process by which an evaluation is made of the necessity, appropriateness, and efficiency of the use of health care services, procedures, or facilities given or proposed to be given to an individual. Such evaluation does not apply to requests by an individual or provider for a clarification, guarantee, or statement of an individual's health insurance coverage or benefits provided under a health benefit plan, nor to claims adjudication. Unless it is specifically stated, verification of benefits, preauthorization, or a prospective or concurrent utilization review program or process shall not be construed as a guarantee or statement of insurance coverage or benefits for any individual under a health benefit plan.

m. "Utilization review organization" means an entity that performs utilization review, other than a health carrier

performing utilization review for its own health benefit plans.

2. *Establishment of step therapy protocols.*

a. A health carrier, health benefit plan, or utilization review organization shall do all of the following when establishing a step therapy protocol:

(1) Use clinical review criteria based on clinical practice guidelines that meet all of the following requirements:

(a) Recommend that particular prescription drugs be taken in the specific sequence required by the step therapy protocol.

(b) Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among members of the panel's writing and review groups by doing all of the following:

(i) Requiring members to disclose any potential conflicts of interest with entities, including health carriers, health benefit plans, utilization review organizations, and pharmaceutical manufacturers, and requiring members to recuse themselves from voting if there is a conflict of interest.

(ii) Using a methodologist to work with the panel's writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and by facilitating consensus.

(iii) Offering opportunities for public review and comments.

(c) Are based on high-quality studies, research, and medical practice.

(d) Are created through an explicit and transparent process that does all of the following:

(i) Minimizes biases and conflicts of interest.

(ii) Explains the relationship between treatment options and outcomes.

(iii) Rates the quality of the evidence supporting the recommendations.

(iv) Considers relevant patient subgroups and preferences.

(e) Are continually updated through a review of new

evidence, research, and newly developed treatments.

(2) Take into account the needs of atypical covered person populations and diagnoses when establishing clinical review criteria.

(3) Notwithstanding subparagraph (1), peer-reviewed publications may be substituted for the use of clinical practice guidelines in establishing a step therapy protocol.

b. This subsection shall not be construed to require health carriers, health benefit plans, utilization review organizations, or the state to establish a new entity to develop clinical review criteria for step therapy protocols.

c. A health carrier, health benefit plan, or utilization review organization shall, upon written request of an insured or prospective insured, provide specific written clinical review criteria relating to a particular condition or disease, including clinical review criteria relating to a request for a step therapy override exception and, where appropriate, other clinical information which the health carrier, health benefit plan, or utilization review organization might consider in its utilization review or in making a determination to approve or deny a request for a step therapy override exception, including a description of how the information will be used in the utilization review process or in making a determination to approve or deny a request for a step therapy override exception. However, to the extent that such information is proprietary to the health carrier, health benefit plan, or utilization review organization, the insured or prospective insured shall only use the information for the purposes of assisting the insured or prospective insured in evaluating the covered services provided by the health carrier, health benefit plan, or utilization review organization. Such clinical review criteria and other clinical information shall also be made available to a health care professional, upon written request made by the health care professional on behalf of an insured or prospective insured.

3. *Exceptions process transparency.*

a. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health benefit plan, or utilization review organization through the use of a step therapy protocol, the covered person and the prescribing health care professional shall have access to a clear, readily accessible, and convenient process to request a step therapy override exception. A health carrier, health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process used shall be easily accessible on the internet site of the health carrier, health benefit plan, or utilization review organization.

b. A step therapy override exception shall be approved expeditiously by a health carrier, health benefit plan, or utilization review organization if any of the following circumstances apply:

(1) The prescription drug required under the step therapy protocol is contraindicated or is likely to cause an adverse reaction or physical or mental harm to the covered person.

(2) The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person and the known characteristics of the prescription drug regimen.

(3) The covered person has tried the prescription drug required under the step therapy protocol while under the covered person's current or a previous health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(4) The prescription drug required under the step therapy protocol is not in the best interest of the covered person, based on medical necessity.

(5) The covered person is stable on a prescription drug selected by the covered person's health care professional for the medical condition under consideration while on the current or a previous health benefit plan.

c. Upon approval of a step therapy override exception, the health carrier, health benefit plan, or utilization review organization shall expeditiously authorize coverage for the prescription drug selected by the covered person's prescribing health care professional.

d. A health carrier, health benefit plan, or utilization review organization shall make a determination to approve or deny a request for a step therapy override exception within five calendar days of receipt of the request for an exception or appeal of a denial of such a request. In cases where exigent circumstances exist, a health carrier, health benefit plan, or utilization review organization shall make a determination to approve or deny the request for an exception or appeal of a denial of such a request within seventy-two hours of receipt of the request for an exception or appeal of a denial of such a request. If a determination to approve or deny the request for an exception or appeal of a denial of such a request is not made within the applicable time period, the request for an exception or appeal of a denial of such a request shall be deemed to be approved.

e. If a determination is made to deny a request for a step therapy override exception, the health carrier, health benefit plan, or utilization review organization shall provide the covered person or the covered person's authorized representative and the covered person's prescribing health care professional with the reason for the denial and information regarding the procedure to appeal the denial. Any determination to deny a request for a step therapy override exception may be appealed by a covered person or the covered person's authorized representative.

f. A health carrier, health benefit plan, or utilization

review organization shall uphold or reverse a denial of a request for a step therapy override exception within five calendar days of receipt of an appeal of the denial. In cases where exigent circumstances exist as provided in paragraph "*d*", a health carrier, health benefit plan, or utilization review organization shall make a determination to uphold or reverse a denial of such a request within seventy-two hours of receipt of an appeal of the denial. If the denial of a request for a step therapy override exception is not upheld or reversed on appeal within the applicable time period, the denial shall be deemed to be reversed and the request for an override exception shall be deemed to be approved.

g. If a denial of a request for a step therapy override exception is upheld on appeal, the health carrier, health benefit plan, or utilization review organization shall provide the covered person or the covered person's authorized representative and the patient's prescribing health care professional with the reason for upholding the denial on appeal and information regarding the procedure to request external review of the denial pursuant to chapter 514J. Any denial of a request for a step therapy override exception that is upheld on appeal shall be considered a final adverse determination for purposes of chapter 514J and is eligible for a request for external review by a covered person or the covered person's authorized representative pursuant to chapter 514J.

4. *Limitations.* This section shall not be construed to do either of the following:

a. Prevent a health carrier, health benefit plan, or utilization review organization from requiring a covered person to try an AB-rated generic equivalent prescription drug prior to providing coverage for the equivalent branded prescription drug.

b. Prevent a health care professional from prescribing a prescription drug that is determined to be medically appropriate.

Sec. 3. APPLICABILITY. This Act is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2018.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to the use of step therapy protocols for prescription drugs by health carriers, health benefit plans, and utilization review organizations, and includes applicability provisions.

The bill includes legislative findings that step therapy protocols are increasingly being used by health carriers, health benefit plans, and utilization review organizations to control health care costs, that step therapy protocols that are based on well-developed scientific standards and flexibly administered can play an important role in controlling health care costs, but that in some cases use of such protocols can have adverse or dangerous consequences for the person for whom the drugs are prescribed. The bill includes findings that uniform policies for the use of such protocols that preserve a health care professional's right to make treatment decisions and that provide for exceptions to the use of such protocols are in the public interest.

The bill defines a "step therapy protocol" as a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular covered person are covered under a pharmacy or medical benefit by a health carrier, a health benefit plan, or a utilization review organization including self-administered drugs and drugs administered by a health care professional.

The bill requires that a step therapy protocol be established using clinical review criteria that are based on specified clinical practice guidelines. A step therapy protocol should take into account the needs of atypical

populations and diagnoses. The bill does not require a health carrier, health benefit plan, utilization review organization, or the state to establish a new entity to develop clinical review criteria for such protocols.

Upon written request of an insured or prospective insured, or upon written request of a health care professional on behalf of such a person, a health carrier, health benefit plan, or utilization review organization shall provide specific written clinical review criteria relating to a particular condition or disease, including criteria relating to a request for a step therapy override exception which might be used in utilization review or in making a determination to approve or deny a request for a step therapy override exception. If the information provided is proprietary the insured or prospective insured shall use it only for purposes of evaluating covered services.

The bill also provides that when a step therapy protocol is in use, the person participating in a health benefit plan or the person's prescribing health care professional must have access to a clear, readily accessible, and convenient process to request a step therapy override exception. A "step therapy override exception" means a step therapy protocol should be overridden in favor of immediate coverage of the prescription drug selected by the prescribing health care professional, based on a review of the request along with supporting rationale and documentation. The bill provides that the request for an exception shall be granted if specified circumstances are determined to exist and coverage for the drug selected by the prescribing health care professional shall be authorized.

A request for a step therapy override exception must be approved or denied by the health carrier, health benefit plan, or utilization review organization utilizing the step therapy protocol within five calendar days of receipt of the request or appeal of a denial of such a request, or within 72 hours

of receipt of the request or appeal of a denial of such a request where exigent circumstances exist. The health carrier, health benefit plan, or utilization review organization can use its existing medical exceptions procedure to satisfy this requirement. If a determination to approve or deny the request or appeal of a denial of such a request is not made within the applicable time period, the request is deemed to be approved.

If a determination is made to deny the request for a step therapy override exception, the health carrier, health benefit plan, or utilization review organization shall provide the person making the request with the reason for the denial and information about the procedure to appeal the denial. Any denial of such a request is eligible for appeal.

Upon appeal, the health carrier, health benefit plan, or utilization review organization shall make a determination to uphold or reverse the denial within five calendar days, or within 72 hours in the case of exigent circumstances, of receiving the appeal. If the denial is not upheld or reversed on appeal within the applicable time period, the denial is deemed to be reversed and the request for an exception is deemed to be approved.

If a denial of a request for a step therapy override exception is upheld on appeal, the person making the appeal shall be provided with the reason for upholding the denial on appeal and information regarding the procedure to request external review of the denial pursuant to Code chapter 514J. A denial of a request for such an exception that is upheld on appeal shall be considered a final adverse determination for purposes of Code chapter 514J and is eligible for a request for external review pursuant to Code chapter 514J.

The bill shall not be construed to prevent a health carrier, health benefit plan, or utilization review organization from requiring a person to try an AB-rated generic equivalent prescription drug prior to providing coverage for the equivalent branded prescription drug, or to prevent a health

care professional from prescribing a prescription drug that is determined to be medically appropriate.

The bill is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2018.